REMARKS/ARGUMENTS

Applicants appreciate the courtesy extended by the Examiner in a brief telephone discussion. During that discussion, certain amendments were discussed for putting the application into better condition for allowance. Pursuant to that telephone discussion and in response to the Office Communication mailed September 14, 2007, Applicants' submit the following Remarks in conjunction with the above Amendment.

CLAIM OBJECTIONS

Each of the Examiner's objections have been addressed. Claims 21, 23 and 29 have been amended to address the Examiner's concerns.

REJECTIONS UNDER 35 USC 101

Claims 27 and 52-56 are rejected under 35 USC 101 as reciting "a bodily fluid sample comprising". Claims 27 and 52 have been amended to now recite a "test strip [that] is configured to sample a submicroliter bodily fluid sample that comprises…", and claims 53-56 have been amended to now recite a "device [that] is configured to sample a bodily fluid sample that comprises…". The rejection is thus overcome.

REJECTIONS UNDER 35 USC 102

Claims 21-35 and 52-56 are rejected as being anticipated by Cunningham et al. (US 6,306,104). This rejection is respectfully traversed. Claim 21 requires that that device is configured such that after lancing and withdrawing of the lancing device, the test strip is movable to a bodily fluid sample contacting position within 0.010 inch of said center of said submicroliter bodily fluid sample.

This is advantageous because Applicants' test strip is best positioned at or near the center of the body fluid sample for receiving a high percentage of available body fluid sample. This is important, because it is desired to be able to test with only a small amount of body fluid sample, such as may be available at an alternative site other than fingertips and/or using a thinner and less painful needle. The ability to position the test strip within a mechanical tolerance of 1/100 of an inch is advantageously achieved in Applicants' invention, and is nowhere described by Cunningham et al. It is moreover submitted that Cunningham et al. simply do not describe a device that is capable of achieving this level of precision.

The Examiner has not even cited any description by Cunningham et al. to meet this advantageous feature of Applicants' invention. There appears to be no such description at any of the sections of Cunningham et al. cited by the Examiner as meeting other recited features of Applicants' invention. The Examiner is respectfully requested to withdrawn this rejection, because Cunningham et al. do not disclose a precision mechanical tolerance of 1/100 of an inch or better, and because this feature provides tremendous advantage to health care providers seeking to test body fluid samples of patients, and/or to patients themselves performing self-care testing on their own bodies.

Applicants have achieved the desired result of accuracy within a tolerance of 1/100 of an inch, or 0.010 inch, which means that the test strip is centered within a 1/100 of an inch tolerance of the center of a body fluid sample. As compared with less accurate conventional devices, Applicants device is able to ensure that sufficient sample is actually applied to the test strip even when only a small submicroliter body fluid sample volume is available. This is particularly advantageous for alternative site testing, i.e., away from the fingertips, as well as when only a small amount of body fluid is available at the fingertip and a patient does not desire to cause more body fluid to emerge through a lancing site. Patients have pricked their fingertips in the past, because they have been able to make a relatively large amount of body fluid available there, which was needed

with conventional devices of the past. However, patients do not wish to prick their sensitive fingertips unless they simply cannot acquire enough body fluid sample by lancing at an alternative site, and even when the fingertip is used, patients would prefer to sample the body fluid that readily emerges rather than painstakingly milking the fingertip for sufficient body fluid sample. Applicants' advantageous high accuracy device helps to more often meet these patients' desires by providing the test strip within a tolerance that is very near the center of the body fluid sample, such that even if the body fluid sample is small, a sufficient amount may still be applied to the test strip to perform an analysis.

In a conventional device not having the accuracy of Applicants' invention, a test strip will be on-average offset from a lancet site, and thus the center of a body fluid sample emerging therefrom, by more than 1/100 of an inch. The result is a greater likelihood of an unsuccessful test than with Applicants' device. Either one or more undesirable re-lances or a re-lance at a fingertip and/or untoward milking would be the necessary aftermath of an unsuccessful test. Applicants' advantageous device having a tolerance within 0.010 inch for locating an edge of a test strip at a center of a submicroliter body fluid sample reduces the painful recurrences of traumatic circumstances such as these.

Unless the Examiner can point specifically to an indication by Cunningham et al. of a 1/100 inch precision in locating a test strip at a center of a lancing site in a device as otherwise recited in Applicants' above claims, then the Examiner is respectfully requested to withdraw this rejection and allow claims 21-35 and 52-56.

In the event that the Examiner disagrees with any of the above, or has any other concerns regarding this application, the Examiner is respectfully requested to call the undersigned attorney at 415-203-2782 or 415-674-6711 or email andy@sfbayareapatents.com to discuss.

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 50-4425. A duplicate page is enclosed.

Respectfully submitted,

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